CLAIMS

1. A sleep regulating system relating to states of consciousness and comprising a pharmaceutical formulation which effects transitions between said states, said formulation generally featuring an initial release which is compatible with onset of drowsiness and slumber, a subsequent delay phase corresponding to a nominal interval of sleep, and a conclusional arousal release promoting reversion to consciousness with ensuant alertness and vigor during early activities, the formulation having a dosage form designed for oral administration before bedtime.

2. The sleep regulating system according to Claim 1 organizationally configured such that the initial transition, from waking to sleep, is effected by an outer component group, and both the delay phase and reversion to the conscious state are accomplished by an inner subsystem.

3. The sleep regulating system according to Claim 2 prepared as a dosage form in which delay of release is effected by any of the various means known to the pharmaceutical art, either as single methods or as combinations thereof.

4. The sleep regulating system according to Claim 2 wherein the outer component group is normally comprised of at least one layer, said layer or layers carrying one or more sleep-compatible substance which is generally arranged for prompt release, and wherein the inner subsystem includes at least one subunit, said subunit being comprised of a coated core, said core containing at least one active wakeup agent and completely enveloped by a coating distinct from any outer component, said coating fabricated from at least one film-forming material and constituting an osmotic semipermeable membrane.

5. The sleep regulating system according to Claim 4 wherein the osmotic semipermeable membrane is characterized by ample but finite elasticity, pharmaceutical inertness, insolubility in aqueous media, permeability to water, impermeability to outward flux of active agent, and the behavior of said membrane, pursuant to ingestion of the dosage form, is progressive expansion by internal pressure in synchronous correlation with residence in the gastrointestinal tract until the membrane bursts, thereby accomplishing delayed release of the wakeup agent.

6. The sleep regulating system according to Claim 5 comprised such that delay is effected by a combination of means or subsystems, including, but not restricted to, semi-permeable membrane rupture after a definite time period, wherein a main membrane surrounds an agglomeration of smaller subunits such as pellets and granules, and optionally said smaller subunits are individually coated by membranes.

7. The sleep regulating system according to Claim 4 wherein the semipermeable membrane features at least one weak spot which, pursuant to absorption of water by the core, ruptures primarily at said weak spot resulting in release of the agent to the gastrointestinal tract, the length of delay from administration to said rupture being at least partially determined by the degree of reduction of strength of the weak spot relative to strength of the other areas of the membrane.

8. The sleep regulating system according to Claim 4 wherein the semipermeable membrane features at least one seam which, pursuant to absorption of water by the core, ruptures primarily along said seam resulting in release of the agent to the gastrointestinal tract, the length of delay from administration to said rupture being at least partially determined by the relatively deficient bond of the seam as compared to the strength of other areas of the membrane.

9. The sleep regulating system according to Claim 4 wherein the principal materials of the semi-permeable membrane may be selected from the group of polymers comprised of organic cellulose esters such as cellulose acetate; inorganic cellulose esters such as cellulose nitrate; cellulose ethers such as ethylcellulose; polyvinyl alcohols; polyurethanes; vinyl esters such as polyvinylacetate and ethylene vinyl acetate; and polyacrylics; but said materials not restricted to selection only from said group, and eligible for any compatible combination as well as single-material compositions.

10. The sleep regulating system according to Claim 4 designed with a plurality of subunits, cores of the subunits formed as pellets, beads, or mini-tablets, each subunit having its own membrane and outer sleep-compatible layer, all of the individual subunits prepared so as to release their contents simultaneously and aggregated by conventional methods such as, but not limited to, filling into capsules and pressing into shaped bodies, and wherein optional arrangements for the outer sleep-compatible component may include powder loading into said conventionally filled capsules, coating of the outer surfaces of conventional capsules, and superposition onto said shaped bodies by the various means known to the art.

11. The sleep regulating system according to Claim 4 wherein the sleep-compatible substance is any selection from the group comprised of tonics, calmatives, hypnotics, muscle relaxants, sedatives, anti-anxiety agents, anti-insomnia agents, tranquilizers, neutral materials having no pharmaceutically active character, hormones, endorphins, herbal preparations, and substances traditionally reputed to have soporific effects, such as but not confined to: benzodiazepines including lorazepam, temazepam, triazolam, their derivatives and close relatives; non-benzodiazepines represented by zaleplon, zolpidem tartrate, L -tryptophan, 5-hydroxy-L-tryptophan, melatonin, sleep-promoting factor, their derivatives, and close relatives; drugs whose availability has been postponed due to detentions such as but not limited to further development, ongoing clinical trials, and FDA review, including eszopiclone which is also known as S-Zopiclone, further including but not restricted to NGD 91-2, NGD 96-3, and NS2710, in addition to indiplon which is also known as NBI-34060.

12. The sleep regulating system according to Claim 4 wherein at least one wakeup agent is selected from the group comprised of pharmaceutically active energizers, invigorants, nervous system stimulants, and psychostimulants, including but not restricted to amphetamines, methylphenidate, venlafaxine, nefazodone, sodium oxybate, adrafinil, modafinil, phentermine, pemoline, adrenaline; methyl xanthines including theophylline, theobromine, and caffeine; substances pending release due to further development, clinical trials, FDA review, or other detention; drugs temporarily withdrawn from availability; as well as close relatives and derivatives of members from said group; all members being eligible for any compatible combination.

13. The sleep regulating system according to Claim 4 wherein pharmaceutical agents for treatment of Attention Deficit Disorder and Attention Deficit Hyperactive Disorder comprise a group from which at least one substance is adapted as a wakeup agent.

14. The sleep regulating system according to Claim 4 wherein the core may include any appropriate conventional excipients known to the art, including gas-generating substances such as, but not restricted to, sodium bicarbonate and calcium carbonate coupled with one or more mild acids such as citric acid and sodium dihydrogen phosphate.

15. The sleep regulating system according to Claim 4 wherein the length of the delay between administration of the dosage form and release of the arousal agent can be programmed by any combination of technical methods comprised from: discretionary selection of specific materials for fabrication of the semipermeable membrane, change of the thickness and thus the permeability of the membrane, supplementation of the core with osmotic attractant, change of the surface area of the subunit, and alteration of the overall dimensions of the subunit, said alteration effected by means such as modification of the radius.

16. A method of preparation for the sleep regulating system according to Claim 4 wherein the subunit cores are fashioned by established, improved, or new pharmaceutical techniques including, but not restricted to, formation as rounded granules by rotor granulation, small tablets by direct compression, and spheres, possibilities for origination of said spheres including colloid gelatination, rounding of extrudates, direct pelletization, and buildup unto pre-fabricated inert bodies such as sugar balls.

17. A method of preparation for the sleep regulating system according to Claim 4 in which the inner subsystem is comprised of a prefabricated time-disintegration tablet or caplet, said tablet or caplet bored to form a hollow space, filled with an active wakeup compound, and re-sealed with a material which effectively restores the integrity of the dosage form and re-enables its delayed release function.

18. The sleep regulating system according to Claim 4 wherein at least one portion of substance is scheduled for release during the delay phase before release of the wakeup agent, said substance selected from the group including but not restricted to complementary therapeutic agents, nutrients, and sleep-assisting agents, options for the character of the substance being identical to, similar to, and different from any initially released agent.

19. The sleep regulating system according to Claim 18, whereby means for interim release of substance may include, but are not restricted to, multiple semipermeable membranes configured to burst in series, the innermost of said membranes being responsible for containment and ultimate release of the wakeup agent.

20. The sleep regulating system according to Claim 1 wherein the lag time between administration and the start of arousal action is, in basic embodiments, optimally in the range of about 5 to 9 hours and preferably about 5 to 7.5 hours.

21. The sleep regulating system according to Claim 1 arranged for a short delay, wherein the nominal interval of sleep is a nap, and thus the lag between administration and the start of stimulus action is optimally in the range of about 2 to 5.5 hours, particular applications for such short delay formulations including, but not restricted to, therapy for incontinence.

22. The sleep regulating system according to Claim 1, wherein the initial release is substituted by a phase featuring no release of a pharmaceutically active agent.

23. The sleep regulating system according to Claim 4 wherein, pursuant to absorption, persistence of the wakeup agent as residual in the bloodstream during elimination enables alertness and vigor in early activities.

24. A method for reducing tardiness and absenteeism, comprised of the pharmaceutical formulation according to Claim 23, whereby positive transition from sleep to wakefulness, assisted by protracted early vigor, constitutes a strong start, said strong start promoting punctual arrival at destinations such as school and employment, and sharply reducing the chance that susceptible individuals might not attend said destinations.

25. The method of Claim 24, suited for students, options for administration including by self and by parent, and further options including provision by schools.

26. The method of Claim 24, purposed to reinforce employment stability of a worker, and applied via self-administration.

27. The method of Claim 24, arranged for an employer, wherein the pharmaceutical formulation is made available by said employer to employees, benefits to the employer upon usage by said employees including, but not limited to, improved business productivity and relief of economic loss, said benefits derived chiefly from reduced dismissals and thus decreased turnover in personnel.

28. The method of Claim 24, projected to moderation of macroeconomic unemployment, benefits upon usage including, but not limited to, decrease in dismissals of workers.

29. A method for treating stress, comprised of administration of the pharmaceutical formulation according to Claim 23; indications for said method often including stress manifest by anxiety disorders, and the method further indicated wherein stress is concurrent with depression; benefits of the formulation which may include, but are not restricted to, consistency of initial organization pursuant to wakeup and reinforced employment surety; the method alternately comprised of the sleep regulating system administered in conjunction with other stress therapies, possibilities for said therapies including anxiolytic drugs as well as non-pharmaceutical stress management strategies.

30. A method for treating depression comprised of the pharmaceutical formulation according to Claim 23 administered to a patient in conjunction with other anti-depressant therapies, the preparation serving to assist punctuality and productive vigor in early waking activities, benefits of said assistance including, but not limited to, improvement of sense of efficacy, said method optionally comprised of the formulation administered independent of other therapies.

31. A method for treating Chronic Fatigue Syndrome comprised of administration of the pharmaceutical formulation according to Claim 23, serving to alleviate symptoms in early activities, said alleviation including compensation for oppressive weariness and inertia, further benefit to afflicted individuals including, but not limited to, assisted punctuality, improved personal safety via reduced probability of drowsing or falling asleep while in transit to work, and correspondingly fortified employment surety, said method optionally comprised of the formulation administered as adjuvant to other therapies which may be available.

32. A treatment for sleep disorders comprised of the sleep regulating system of Claim 23, wherein symptoms of said disorders include detrimental patterns such as sequences or circles of sleep inadequacy accompanied by difficulty in awakening at a reasonably scheduled time point, and whereby the system weakens, and, optimally, disrupts, said patterns.

33. A treatment for Insomnia and sleep disorders which include insomnia as a symptom, comprised of the sleep regulating system of Claim 23, by which, in addition to initial insomnia being addressed per release of calmative or other sleep-compatible substance, the integral formulation harmonizes the overall sleep cycle, said harmonization accomplished collaboratively by the conclusional release, residual arousal agent from which, pursuant to assisting wakeup, promotes vigor and productivity in early waking activities, the treatment thus reducing compulsions to ingest stimulants later in the day and immerse in agitating engagements before bedtime, and thereby diminishing sources of the insomnia.

34. The treatment according to Claim 33 wherein at least one portion of calmative or other sleep-compatible substance is arranged for interim release during the delay phase, said portion addressing middle insomnia, and said interim release arrangement optionally featuring no initial release of sleep-compatible agent.

35. A treatment for sleep disorders principally including, but not confined to, Hypersomnia and Sleep Paralysis, comprised of the sleep regulating system of Claim 23, wherein not only is difficulty in making transition from sleep to wakefulness addressed by the conclusional release of arousal agent, but the overall sleep cycle is attuned via the integral formulation, said tuning achieved in some measure per the initial release, the calmative or other sleep-compatible substance from which helps the suffering individual to overcome any incidental initial insomnia as may occur, said insomnia being a possible primary or contributing cause of said principal sleep disorders.

36. The treatment according to Claim 35 wherein at least one portion of calmative or other sleep-compatible substance is arranged for release during the delay phase, said portion addressing middle insomnia, the formulation optionally featuring no initial release of sleep-compatible agent.

37. An aid to a motor vehicle operator for driving which is executed early in said operator's day or waking hours, said aid especially valuable to a driver younger than about 31 years old, and comprised of the pharmaceutical formulation according to Claim 23 administered prior to sleep which precedes said driving, whereby alertness during vehicle operation reduces probability of involvement of the operator in a traffic accident.

38. A method for reducing traffic accident statistics, based upon the aid of Claim 37, wherein the aid is made easily accessible and widely available to motor vehicle operators, through such as, but not restricted to, driver licensing offices, vehicle dealerships, places of employment, and educational institutions.